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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Yasuhiko ONISHI et al.** Group Art Unit: **2613**

Application Number: **10/536,901** Examiner: **Liam Heincer**

Filed: **May 27, 2005** Confirmation Number: **6263**

For: **CATIONIC GRAFT-COPOLYMER FOR NON-VIRAL GENE DELIVERY VECTOR**

Attorney Docket Number: **052603**
Customer Number: **38834**

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

December 18, 2007

Sir:

I, Yasuhiko Onishi, a citizen of Japan, hereby declare and state the following:

1. I graduated from Hiroshima University of West Hiroshima City, Hiroshima Prefecture, Japan in 1967 with a bachelor degree in engineering.

2. Since 2005, I have been employed by Ryujyu Science Corporation of Seto City, Aichi Prefecture, Japan where my present title is director. During my employment therein, I have conducted research and development.

3. I am the author of the following publications:

"Characteristics of 2-diethylaminoethyl(DEAE)-dextran-MMA graft copolymer as a non-viral gene carrier", Nanomedicine: Nanotechnology, Biology, and Medicine, 3:184-191, 2007.

4. I have read and am familiar with the above-identified patent application as well as the Official Action dated September 19, 2007, in the application.

5. I have read and am familiar with the contents of cited references, U. S. Patent Nos. 4,816,540 to Onishi; and "Gene-Delivery Polymers" to Park cited in the Official Actions in the above-identified application.

6. Under my supervision and control, I conducted experiments to obtain data for illustrating the efficacy/transfection efficiency of the claimed non-viral gene delivery vector comprising the graft copolymer as compared with prior known vectors for this particular purpose.

7. In the data, Example 1 (DDMC) is compared with PolyFect Reagent (QIAGEN GmbH) having dendrimeric structures shown in Section 2.2.2 of Pack (Gene delivery polymers). The data is for transfection for COS7 cells by pGL3DNA/DDMC. The cells were ready to harvest 72 hours after the transfection, and were then assayed for luciferase activity. The results are presented in the attached graph.

8. From the attached experimental results, I have concluded, among other things, that the claimed non-viral gene delivery vector has a higher transfection efficacy/transfection efficiency as compared with the prior known vectors.

Declaration under 37 C.F.R. §1.132
Application No. 10/536,901
Attorney Docket No. 052603

The undersigned declares that all statements made herein of his own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of the application or any patent issued thereon.

Yasuhiko Onishi

Yasuhiko Onishi

Signed this 18 day of December, 2007.

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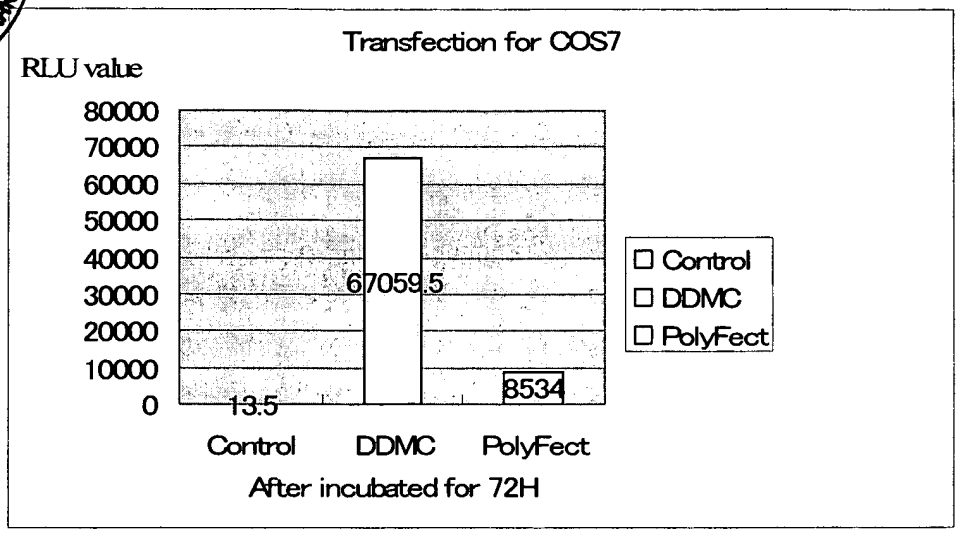

The transfection for COS7 cells was carried out by pGL3DNA/DDMC .

Cells are ready to harvest 72 hours post- transfection and assayed for luciferase activity.